UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: October 17, 2017

Subject: Efficacy Review for Force of Nature Activator Capsule, EPA File Symbol 93040-R (DP Barcode: 441522)

From: Alison Clune
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Kristen Willis, Acting Team Leader
Product Science Branch
Antimicrobials Division (7510P)

To: Demson Fuller, PM 31 / Benjamin Chambliss
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: HCI Cleaning Products, LLC

Agent: KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256

Formulation from the Label:

Active Ingredient(s)	% by wt.
Sodium Chloride	20.9%
Other Ingredients	79.1%
Total	100.0%

I BACKGROUND

Product Description (as packaged, as applied): Capsule used with a device to produce an active electrolyzed water solution, applied as a liquid

Submission type: New product

Requested efficacy claim(s): hospital disinfectant (bactericidal, virucidal, fungicidal); food contact surface sanitizer.

Documents considered in this review:

- Letter from applicant's agent to EPA dated May 19, 2017
- Proposed label and device user guide, no printed date, dated 5-20-17 in the file name
- 7 efficacy studies (MRIDs 50290708-50290714)
- 2 chemistry studies supporting efficacy claims (MRIDs 50290705 and 50290707)
- Proposed basic Confidential Statement of Formula (EPA Form 8670-4) dated 5/17/17
- Email correspondence in response to technical screen sent from Kevin Kutcel on 8/23/17 and 9/19/17 including:
    - 2 letters from applicant to EPA dated August 19, 2017 and September 19, 2017
    - 2 letters from the efficacy testing lab to the applicant dated August 21, 2017 and September 19, 2017.

II PROPOSED DIRECTIONS FOR USE

"**DIRECTIONS FOR USE OF FORCE OF NATURE ACTIVATOR CAPSULE (TO GENERATE HYPOCHLOROUS ACID SOLUTION)…**

1. Fill Force of Nature Activator Bottle to fill line with tap water (347 gm).
2. Add one Force of Nature Activator Capsule (3.35 gm) to Bottle. (Use only Force of Nature Activator Capsules when making Electrolyzed Water Solution)
3. Close lid.
4. Place Bottle in Force of Nature Activator Base
5. Press "Start" button

This process generates a Hypochlorous Acid solution of 220 ppm Available Chlorine."

"**DIRECTIONS FOR USE OF HYPOCHLOROUS ACID SOLUTION…**

To Clean and Disinfect and Deodorize Hard, Non-Porous Surface: Clean surface. Apply Force of Nature disinfecting solution to hard non-porous, non-food contact surface, with cloth, wipe, mop or sprayer. Allow surface to remain wet for 10 minutes. Wipe surface with clean cloth or towel or let air dry.

Solution(s) are effective for up to 14 days from production date. After 14-days discard and refill bottle with fresh solution. Always use a Force of Nature approved spray bottle and label to identify product in use."

III STUDY SUMMARIES

1.	MRID	50290705	**Study Completion Date:**	2/9/17
Study		Preliminary Analysis of Device Output Samples		
Test Substance Preparation	**Name/ID**	Force of Nature Electrolyzed Water		
	Lots	FON1701-1-170209 FON1701-2-170209 FON1701-3-170209 FON1701-4-170209 FON1701-5-170209		
	Lot Generation	Input concentration: Not reported Output concentration targeted: Nominal (220 ppm) Dilution analyzed: Ready-to-use # Devices: Not reported # Input lots: Not reported # Output lots: 1 per device, 5 total Device operation parameters: Not reported		
Titration Method		Potassium iodide followed by citric acid and adipic acid, total available chlorine measured with Lovibond MD100 spectrophotometer, measured in duplicate		
Testing Lab, Lab Study ID		DH Owens Enterprises, None		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		The titration method *does not* appear to be the same as the enforcement analytical method for the device output as described in MRID 50290706.		

NR = Not Reported

2.	MRID	50290707	**Study Completion Date:**	3/1/17
Study		Long Term Storage Stability of Device Output Samples		
Test Substance Preparation	**Name/ID**	Force of Nature Electrolyzed Water		
	Lots	FON1701-4-170209		
	Lot Generation	Input concentration: Not reported Dilution analyzed: Ready-to-use # Devices: Not reported # Input lots: Not reported # Output lots: 1 Device operation parameters: Not reported		
Storage Conditions		PET container, room temperature, 14 days, in storage cabinet. Recorded physical state of test substance, corrosion of container, weight of sample, and concentration of available chlorine (in duplicate) on days 0, 3, 6, 10, and 14.		
Testing Lab, Lab Study ID		Accuratus Lab Services, A22604		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		The titration method was the enforcement analytical method for the device output as described in MRID 50290706.		

Note on test substance preparation: Test substances used in the efficacy studies were prepared in two groups, as described in two letters from the applicant to EPA dated August 19, 2017 and September 19, 2017. Group 1 (Lots FON1701-2-170209, FON1701-3-170209, FON1701-4-170209) was prepared at the testing lab using one lot of the input material (Lot #6FON01) at the nominal concentration and municipal tap water from Salisbury, MD. Group 2 (Lots FON1701-3-170320, FON1701-4-170320) was prepared at DH Owens Enterprises using one lot of the input material (Lot #6FON01) at the nominal concentration and municipal tap water from Salisbury, MD. Hardness of the input water at the time and location of collection or use was not reported (a range of pH, hardness, and TDS was provided from the municipal treatment plant). Amounts of input material used, device cycle-time, and/or other relevant operational parameters were not reported.

3.	**MRID**	50290708	**Study Completion Date:**		4/14/17		
Test organism(s) **☐ 1 ☐ 2 ☒ 3 ☐ 4+**		*Pseudomonas aeruginosa* (ATCC 15442) *Staphylococcus aureus* (ATCC 6538) *Salmonella enterica* (ATCC 10708)					
Test Method		AOAC Germicidal Spray Method					
Application Method		Spray					
Test Substance Preparation	**Name/ID**	Force of Nature Electrolyzed Water					
	Lots **☐ 1 ☐ 2 ☒ 3**	FON1701-2-170209 FON1701-3-170209 FON1701-4-170209		FON1701-3-170320 FON1701-4-170320			
	Preparation	Tested concentration: LCL Dilution: Ready-to-use (220 ppm) Diluent: NA		Tested concentration: LCL Dilution: 1902.93g test substance (217ppm FAC) + 416.93g diluent; 1907.23g test substance (226ppm FAC) + 525.07g diluent Diluent: Deionized water			
Soil load		None					
Carrier type, # per lot		Glass slides, 60					
Test conditions		**Contact time**	10 minutes	**Temp**	20˚C	**RH**	11-21%
Testing Lab, Lab Study ID		Accuratus Lab Services, A22635					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		The dilution of lots FON1701-3-170320 and FON1701-4-170320 was described in a letter from the efficacy testing lab to the applicant dated September 19, 2017. On 2/23/17, testing of Lot FON1701-4-170209 against *Salmonella enterica* failed due to two contaminants confirmed not to be the test organism. Testing was repeated on 3/22/17 with an additional lot of test substance (FON1701-3-170320). On 2/23/17 testing of Lots FON1701-2-170209 and FON1701-3-170209 against *Staphylococcus aureus* did not meet efficacy requirements. Testing was repeated on 3/22/17 with two additional lots of test substance (FON1701-3-170320 and FON1701-4-170320).					

4.	**MRID**	50290709	**Study Completion Date:**		4/14/17		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Listeria monocytogenes* (ATCC 19117)					
Test Method		AOAC Germicidal Spray Method					
Application Method		Spray					
Test Substance Preparation	**Name/ID**	Force of Nature Electrolyzed Water					
	Lots **☐ 1 ☒ 2 ☐ 3**	FON1701-2-170209 FON1701-3-170209					
	Preparation	Tested concentration: LCL Dilution: Ready-to-use (220 ppm) Diluent: NA					
Soil load		None					
Carrier type, # per lot		Glass slides, 10					
Test conditions		**Contact time**	10 minutes	**Temp**	20˚C	**RH**	23%
Testing Lab, Lab Study ID		Accuratus Lab Services, A22636					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None					

5.	**MRID**	50290710	**Study Completion Date:**		4/14/17		
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Methicillin Resistant *Staphylococcus aureus* – MRSA (ATCC 33592)					
Test Method		AOAC Germicidal Spray Method					
Application Method		Spray					
Test Substance Preparation	**Name/ID**	Force of Nature Electrolyzed Water					
	Lots **☐ 1 ☒ 2 ☐ 3**	FON1701-2-170209 FON1701-3-170209					
	Preparation	Tested concentration: LCL Dilution: Ready-to-use (220 ppm) Diluent: NA					
Soil load		None					
Carrier type, # per lot		Glass slides, 10					
Test conditions		**Contact time**	10 minutes	**Temp**	20.1˚C	**RH**	23%
Testing Lab, Lab Study ID		Accuratus Lab Services, A22637					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic sensitivity testing conducted at Accuratus Lab Services by Kirby Bauer assay. Strain demonstrated resistance to oxacillin.					

6.	MRID	50290711	Study Completion Date:	4/24/17
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Salmonella enterica* subspecies *enterica* serovar Typhi (ATCC 6539)		
Test Method		AOAC Available Chlorine in Disinfectants		
Application Method		Liquid (suspension test)		
Test Substance Preparation	**Name/ID**	Force of Nature Electrolyzed Water		
	Lots **☐ 1 ☐ 2 ☒ 3**	FON1701-2-170209 FON1701-3-170209 FON1701-4-170209		
	Preparation	Tested concentration: LCL Dilution: Ready-to-use (220 ppm) Diluent: NA		
Soil load		None		
Carrier type, # per lot		NA		
Test conditions		**Contact time** NA	**Temp** 20.0˚C	**RH** NA
Testing Lab, Lab Study ID		Accuratus Lab Services, A22702		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None		

7.	MRID	50290712	Study Completion Date:	4/24/17
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Influenza A Virus, Strain A/Hong Kong/8/68 (ATCC VR-544)		
Test Method		ASTM E1053		
Application Method		Spray		
Test Substance Preparation	**Name/ID**	Force of Nature Electrolyzed Water		
	Lots **☐ 1 ☒ 2 ☐ 3**	FON1701-2-170209 FON1701-3-170209		
	Preparation	Tested concentration: LCL* Dilution: Ready-to-use (220 ppm) Diluent: NA		
Soil load		1% fetal bovine serum		
Carrier type, # per lot		Glass petri dishes, 1		
Test conditions		**Contact time** 10 minutes	**Temp** 20.0˚C	**RH** NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A22691		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		*The study report indicates that the test substance was diluted by the analytical chemistry lab, however the diluent and dilution procedure were not described in the study report. The concentration reported on the certificate of analysis (COA) indicates that the test substance was below the LCL. It is not clear from the study report whether the dilution was performed before or after the analysis indicated on the COA, and the diluent is not described.		

NR = Not Reported

8.	**MRID**	50290713	**Study Completion Date:**			4/18/17	
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Feline Calicivirus, Strain F9 (ATCC VR-782)					
Test Method		ASTM E1053					
Application Method		Spray					
Test Substance Preparation	**Name/ID**	Force of Nature Electrolyzed Water					
	Lots **☐ 1 ☒ 2 ☐ 3**	FON1701-2-170209 FON1701-3-170209					
	Preparation	Tested concentration: LCL* Dilution: Ready-to-use (220 ppm) Diluent: NA					
Soil load		1% fetal bovine serum					
Carrier type, # per lot		Glass petri dishes, 2					
Test conditions		**Contact time**	10 minutes	**Temp**	20.0˚C	**RH**	NR
Testing Lab, Lab Study ID		Accuratus Lab Services, A22690					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		*The study report indicates that the test substance was diluted by the analytical chemistry lab, however the diluent and dilution procedure were not described in the study report. The concentration reported on the certificate of analysis (COA) indicates that the test substance was below the LCL. It is not clear from the study report whether the dilution was performed before or after the analysis indicated on the COA, and the diluent is not described.					

NR = Not Reported

9.	**MRID**	50290714	**Study Completion Date:**			4/24/17	
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Trichophyton mentagrophytes* (ATCC 9533)					
Test Method		AOAC Germicidal Spray Method					
Application Method		Spray					
Test Substance Preparation	**Name/ID**	Force of Nature Electrolyzed Water					
	Lots **☐ 1 ☒ 2 ☐ 3**	FON1701-2-170209 FON1701-3-170209					
	Preparation	Tested concentration: LCL Dilution: Ready-to-use (220 ppm) Diluent: NA					
Soil load		None					
Carrier type, # per lot		Glass slides, 10					
Test conditions		**Contact time**	10 minutes	**Temp**	18.4˚C	**RH**	69%
Testing Lab, Lab Study ID		Accuratus Lab Services, A22704					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None					

IV STUDY RESULTS

Device Output – Active Ingredient Concentration (MRID 50290705)

Lot	**Average Available Chlorine (ppm)**
Nominal Concentration on label	*220*
FON1701-1-170209	215
FON1701-2-170209	229
FON1701-3-170209	238
FON1701-4-170209	237
FON1701-5-170209	225
Expected range of output concentration (based on standard certified limits)	*198-242*
Actual range of output concentration	215-238

Device Output – 14-Day Stability of the Active Ingredient (MRID 50290707)

Lot	FON1701-4-170209		
Day	**Available Chlorine (ppm)**	**Average Available Chlorine (ppm)**	**pH**
0	241	241	6.82
	240		
3	225	225	6.88
	225		
6	221	222	6.83
	222		
10	212	211	6.88
	210		
14	204	205	6.99
	205		
Average difference at 14 days (difference as a percent of Day 0 average concentration)		-36 (15%)	
Difference between standard lower certified limit and lowest concentration (difference as a percent of LCL)		+7 (4%)	

Disinfection – Bactericidal Efficacy

MRID	Organism	No. Exhibiting Growth/Total No. Tested					Average log_{10} CFU/Carrier
		FON1701-2-170209	FON1701-3-170209	FON1701-4-170209	FON1701-3-170320	FON1701-4-170320	
10 minute contact time, RTU (220 ppm), no soil							
50290708	*Pseudomonas aeruginosa (*ATCC 15442)	0/60	0/60	1*/60	--	--	6.06
	Staphylococcus aureus (ATCC 6538)	2/60	5/60	0/60	--	--	5.22
		--	--	--	1/60	0/60	5.03
	Salmonella enterica (ATCC 10708)	0/60	0/60	3*/60	--	--	6.00
		--	--	--	0/60	--	5.77
50290709	*Listeria monocytogenes* (ATCC 19117)	1˚ = 0/10 2˚ = 0/10	1˚ = 0/10 2˚ = 0/10	--	--	--	6.16
50290710	Methicillin Resistant *Staphylococcus aureus* – MRSA (ATCC 33592)	0/10	0/10	--	--	--	5.51

*Carrier showed growth that was confirmed not to be the test organism based on colony morphology, Gram stain, and biochemical assay.

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results		Dried Virus Control (Log_{10} TCID/carrier)
			FON1701-2-170209	FON1701-3-170209	
10 minutes, 1% serum, RTU (220 ppm)					
50290712	Influenza A Virus, Strain A/Hong Kong/8/68 (ATCC VR-544)	10^{-1} to 10^{-8} dilution	Complete inactivation	Complete inactivation	5.25
		Log_{10} TCID/carrier	≤0.50	≤0.50	
		Log Reduction	≥4.75	≥4.75	
50290713	Feline Calicivirus, Strain F9 (ATCC VR-782)	10^{-1} to 10^{-4} dilution	Complete inactivation*	Complete inactivation*	4.79357*
		Log_{10} TCID/carrier	≤0.50*	≤0.50*	
		Log Reduction	≥4.79*	≥4.79*	

*Both replicates

Disinfection – Fungicidal Efficacy

MRID	Organism	No. Exhibiting Growth/Total No. Tested		Average log_{10} CFU/Carrier
		FON1701-2-170209	FON1701-3-170209	
10 minute contact time, RTU (220 ppm), no soil				
50290714	*Trichophyton mentagrophytes* (ATCC 9533)	1˚ = 0/10 2˚ = 1*/10	1˚ = 0/10 2˚ = 0/10	4.21

*Carrier showed growth that was confirmed not to be the test organism based on colony morphology and lactophenol cotton blue stain.

Food Contact Surface Sanitization Efficacy (MRID 50290711)

Organism		*Salmonella enterica* subspecies *enterica* serovar Typhi (ATCC 6539)									
Initial Suspension Control		6.7×10^8									
Substance	**Concentration or Lot**	**Subculture Number**									
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
NaOCl Control	200 ppm	0	0	0	0	+	+	+	+	+	+
	100 ppm	0	0	+	+	+	+	+	+	+	+
	50 ppm	0	+	+	+	+	+	+	+	+	+
RTU (220 ppm), no soil											
Force of Nature Electrolyzed Water	FON1701-2-170209	0	0	0	0	0	0	+	+	+	+
	FON1701-3-170209	0	0	0	0	0	0	+	+	+	+
	FON1701-4-170209	0	0	0	0	0	+	+	+	+	+

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50290708, 50290709, 50290710	Disinfectant, bactericidal	Hard, non-porous surfaces	Spray, RTU (220 ppm)	10 minutes	None	None, or deionized water	• *Pseudomonas aeruginosa (*ATCC 15442) • *Salmonella enterica* (ATCC 10708) • *Listeria monocytogenes* (ATCC 19117) • Methicillin Resistant *Staphylococcus aureus* – MRSA (ATCC 33592)	**No[1]**
50290708	Disinfectant, bactericidal	Hard, non-porous surfaces	Spray, RTU (220 ppm)	10 minutes	None	None, or deionized water	• *Staphylococcus aureus* (ATCC 6538)	**No[1,2]**
50290712, 50290713	Disinfectant, virucidal	Hard, non-porous surfaces	Spray, RTU (220 ppm)	10 minutes	None	Not described	• Influenza A Virus, Strain A/Hong Kong/8/68 (ATCC VR-544) • Feline Calicivirus, Strain F9 (ATCC VR-782)	**No[1,3]**
50290714	Disinfectant, fungicidal	Hard, non-porous surfaces	Spray, RTU (220 ppm)	10 minutes	None	None	• *Trichophyton mentagrophytes* (ATCC 9533)	**No[1]**

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50290711	Sanitizer, food-contact surfaces	Hard, non-porous surfaces	Spray, RTU (220 ppm)	NA	None	None	• *Salmonella enterica* subspecies *enterica* serovar Typhi (ATCC 6539)	**No[1]**

1. The preparation of the test substance was not fully described in the study reports or additional correspondence. A complete description would include weights and/or volumes of inputs (reagents) used in the device, analysis of the concentration of precursors to the active ingredient(s) in the device inputs (in this case, NaCl concentration in the capsule), hardness and pH of any water used in the device, device cycle-time, and any other parameters (especially those that can be modified by the end user) that are essential to the production of the active ingredient in the device output.

2. Retesting of the 2 batches that failed to meet the performance standard against *Staphylococcus aureus* is not acceptable using the same test conditions. No contamination was present and all controls met acceptance criteria.

3. The tested concentration of the active ingredient was not clear in the study reports. The study report indicates that the test substance was diluted by the analytical chemistry lab, however the diluent and dilution procedure were not described in the study report. The concentration reported on the certificate of analysis (COA) indicates that the test substance was below the LCL, but it is not clear from the study report whether the dilution was performed before or after the analysis indicated on the COA, and the diluent is not described.

VI LABEL COMMENTS

Label Date/Identification Number: Proposed label and device user guide, no printed date, dated 5-20-17 in the file name

1. The proposed label claims that the product, Force of Nature Activator Capsule, when used with the Force of Nature Appliance as one capsule (3.35g) with 347g tap water, produces a solution of 220 ppm available chlorine (i.e. device output).

   This claim is **not acceptable** based on the submitted data. The results of MRID 50290705 demonstrated active ingredient concentrations within the standard certified limits of the proposed label concentration (198-242 ppm available chlorine). However, the study was not conducted under Good Laboratory Practices. The study report did not describe the preparation of the tested substances in order to determine that it was consistent with the proposed label instructions. In addition, the study report did not indicate the number of devices or product lots used to generate the tested samples to determine whether the samples adequately represent the expected variability in the device output concentration. Further, the titration method used in the study was not the enforcement analytical method as described in MRID 50290706.

2. The proposed label claims that the device output at the ready-to-use concentration (220 ppm available chlorine) is effective up to 14 days after production when stored in a cool, dark area in the provided closed spray bottle.

   This claim is **not acceptable** based on the submitted data. The results of MRID 50290707 demonstrated active ingredient concentrations within the standard certified limits of the proposed label concentration (198-242 ppm available chlorine) over 14 days in storage under the proposed conditions. However, the study report did not describe the preparation of the tested substance in order to determine that it was consistent with the proposed label instructions.

3. The proposed label claims that the device output at the ready-to-use concentration (220 ppm available chlorine), when applied as a liquid, is an effective hospital disinfectant with bactericidal activity on pre-cleaned, hard, non-porous surfaces at a 10-minute contact time against the following:

   *Pseudomonas aeruginosa (*ATCC 15442)
   Staphylococcus aureus (ATCC 6538)
   Salmonella enterica (ATCC 10708)
   Listeria monocytogenes (ATCC 19117)
   Methicillin Resistant *Staphylococcus aureus* – MRSA (ATCC 33592)

   These claims are **not acceptable** based on the submitted data. The study reports did not describe the preparation of the tested substances in order to determine that it was consistent with the proposed label instructions. In addition, the product was tested as a spray, and this testing cannot be bridged to a liquid application. All directions for disinfection should direct the user to apply the product as a spray.

   If information about the test substance can be provided, it should also be noted that testing against *Staphylococcus aureus* did not meet the performance criteria for disinfection. Retesting against the same organism under the same conditions is not

allowed when testing is conducted correctly, contamination is not present, and controls meet acceptance criteria. Therefore, this product may not claim to be effective as a hospital or broad spectrum disinfectant according to the proposed use directions. Because testing against *Salmonella enterica* was acceptable, this product could claim effectiveness as a limited spectrum disinfectant for gram negative bacteria and list only *Salmonella enterica* and *Pseudomonas aeruginosa* as disinfection organisms, provided that information about the test substance preparation is reviewed and accepted.

4. The proposed label claims that the device output at the ready-to-use concentration (220 ppm available chlorine), when applied as a liquid, is an effective disinfectant with virucidal activity on pre-cleaned, hard, non-porous surfaces at a 10-minute contact time against the following:

   Influenza A Virus, Strain A/Hong Kong/8/68 (ATCC VR-544)
   Feline Calicivirus, Strain F9 (ATCC VR-782)

   These claims are **not acceptable** based on the submitted data. The study reports did not describe the preparation of the tested substances in order to determine that it was consistent with the proposed label instructions. In addition, the tested concentration of the active ingredient was not clear in the study reports. Further, the product was tested as spray, and this testing cannot be bridged to a liquid application. All directions for disinfection should direct the user to apply the product as a spray.

   If information about the test substance can be provided, it should also be noted that this product cannot claim effectiveness as a virucidal disinfectant because it did not demonstrate effectiveness against the base disinfection bacteria (i.e. *Staphylococcus aureus*). Virucidal claims may not be added to limited spectrum disinfectant products.

5. The proposed label claims that the device output at the ready-to-use concentration (220 ppm available chlorine), when applied as a liquid, is an effective disinfectant with fungicidal activity on pre-cleaned, hard, non-porous surfaces at a 10-minute contact time against the following:

   Trichophyton mentagrophytes (ATCC 9533)

   These claims are **not acceptable** based on the submitted data. The study reports did not describe the preparation of the tested substances in order to determine that it was consistent with the proposed label instructions. In addition, the product was tested as spray, and this testing cannot be bridged to a liquid application. All directions for disinfection should direct the user to apply the product as a spray.

   If information about the test substance can be provided, it should also be noted that this product cannot claim effectiveness as a fungicidal disinfectant because it did not demonstrate effectiveness against the base disinfection bacteria (i.e. *Staphylococcus aureus*). Fungicidal claims may not be added to limited spectrum disinfectant products.

6. The proposed label claims that the device output at the ready-to-use concentration (220 ppm available chlorine) is an effective sanitizer on pre-cleaned, hard, non-porous, food contact surfaces at an unspecified contact time against the following:

   Salmonella enterica subspecies *enterica* serovar Typhi (ATCC 6539)

   These claims are **not acceptable** based on the submitted data. The study reports did not describe the preparation of the tested substances in order to determine that it was consistent with the proposed label instructions.

   If information about the test substance can be provided, it should also be noted that there are no directions for use as a food contact surface sanitizer on the proposed label.

7. Make the following changes to the proposed label:
   a. **Remove all public health claims from the product label.**

      Note to PM: The efficacy reviewer did not conduct a full label review because no public health claims were accepted. If additional information is provided to resolve any of the data deficiencies noted in this review, EET would need to conduct a full label review in addition to reviewing the data.